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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,980	07/23/2001	Takayuki Suzuki	53375/1439	2298

23838 7590 04/21/2003

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WASHINGTON, DC 20005

EXAMINER

MULCAHY, JOHN M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 04/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

# Office Action Summary

Application No.

09/909,980

Applicant(s)

SUZUKI ET AL.

Examiner

John M. Mulcahy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-12 and 20 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 8-12 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Election/Restrictions***

1. Applicant's election without traverse of Group I and the species of Figs. 28-30 in Paper No. 8 is acknowledged. Claim 7 is withdrawn\* from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4, 6-12 and 20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Apparatus claims 1 and 12 describe the claimed apparatus in terms of its engagement with the body of a human being. Claim 1 positively recites "a holding device ... holding a point of a digestive wall ..." and "a suture passing through the digestive wall ...." And claim 12 positively recites that "the holding device holds the junction of a stomach and a[n] esophagus ..." and "the first needle is positioned in the oral side of the junction." Therefore, whether an apparatus falls within the scope of the claims cannot be ascertained until the apparatus is engaged with a human being. However, a claim including within its scope a human being is not patentable subject matter under 35 U.S.C. 101. See 1077 O.G. 24 (Apr. 21, 1987).

Although such references would be proper in claims drawn to a surgical method (e.g., canceled claims 16-19), they are improper in claims drawn to an apparatus. In action on the merits, all positive reference to the body of a human being were construed as functional, i.e., merely requiring the capability of engagement as claimed.

### ***Claim Objections***

3. Claims and 12 are objected to because of the following grammatical informalities:

In claim 2, line 3, it is believed that "has" should be –has been–.

In claim 8, line 2, it is believed that "is" should be deleted.

In claim 12, line 1, it is believed that "when" should be deleted.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4 and 8-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Matsui et al. (6,352,503) which shows an apparatus comprising:

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\* Although Applicant lists claim 7 as reading on the elected species of Figs. 28-30, the description of that species places the first and second needles on the second endoscope, and not on the first as required by

As to claim 1: a first endoscope 1 insertable from the mouth into a body cavity; a holding device 186 extending out of the distal end of the first endoscope capable of holding a point of a digestive wall of the body cavity where an artificial valve is formed (Figs. 44-47); a first needle 51 being movable in a longitudinal direction of the first endoscope and including a sharp end capable of penetrating the digestive wall from the oral side of the point to the anal side of the point (Fig. 11); a suture 52 for passing through the digestive wall following the first needle; and a suture retaining 53 device having a grasping section capable of grasping the suture after it has passed through the digestive wall (Fig. 11).

As to claim 3: the holding device 186 includes two jaws movable between an opened position and a closed position (described as "forceps," col. 17, line 29).

As to claim 4: the first needle has a hollow space disposed therein (for passage of the thread 52; see col. 9, lines 21-22).

As to claim 8: a guide member (either an external guide member, e.g., 36, or internal channel, e.g., 141) having a through hole is provided side by side with the holding device; wherein the suture retaining device 53 is movable in the through hole of the guide member.

As to claim 9: the suture retaining device 53 includes two jaws movable between an opened position and a closed position (described as "forceps," col. 9, line 24).

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As to claim 10: a second endoscope (Fig. 11), the first needle extended from a distal end of the second endoscope.

As to claim 11: the first needle is movable in a position nearer the handle section of the endoscope than the distal end of the endoscope is (needle treating tool 51 is retractable back through the channel of the endoscope; see col. 9, lines 20-21).

As to claim 12: the holding device 186 is capable of holding the junction of a stomach and an esophagus (Figs. 44-47), and the first needle is positionable in the oral side of the junction (Fig. 11).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

a. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsui et al. (6,352,503) as applied to claim 1 above, and further in view of Mangum (5,397,326).

Matsui et al. fails to show a knot pushing device. However, Mangum shows an analogous endoscopic knot pushing device for moving a knot of the suture, which is formed outside the body cavity after the suture has pulled out from the body cavity by

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the suture retaining device, into the body cavity (col. 1, lines 52-64). It would have been obvious to the artisan to employ such a knot pusher with the Matsui et al. endoscope since Mangum teaches that such would allow the sutures to be tied with a convenient technique.

b. Claims 6 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsui et al. (6,352,503) as applied to claim 1 above, and further in view of Mills et al. (5,037,021).

Matsui et al. fails to show a second needle. However, Mills et al. shows an analogous endoscope (Fig. 8) having first 20 and second 30 needles positioned side by side and spaced apart by a certain distance (Fig. 6 embodiment). It would have been obvious to the artisan to modify Matsui et al. by using the sewing machine of Mills et al. since Mills et al. teaches that such would allow the sutures to be tied with a convenient technique.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John M. Mulcahy whose telephone number is (703) 308-3134. The examiner can normally be reached on M-F, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. M. Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

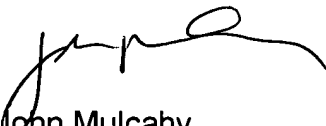
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872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0873.



John M. Mulcahy  
April 14, 2003

John M. Mulcahy  
Primary Examiner  
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